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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,777	02/16/2001	Madhukar Matthew Thakur	THA01-C1003	5209

23973 7590 03/05/2004

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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24358 7590 07/14/2003

THOMAS JEFFERSON UNIVERSITY
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SUITE 620
PHILADELPHIA, PA 19107

EXAMINER

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Office Action Summary

Application No.

09/763,777

Applicant(s)

THAKUR, MADHUKAR MATTHEW

Examiner

D. L. Jones

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

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APPLICANT'S INVENTION

1. Applicant's invention is directed to a composition having formulae I or II as set forth in independent claim 1. Also, Applicant has a claim directed to a method of thrombus imaging as set forth in independent claim 9.

Note: Claim 1-9 are pending.

112 REJECTIONS

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 6 - 7: The claim as written is ambiguous because it is unclear what Applicant intends by the phrase 'or fragment thereof'. Is Applicant stating that the peptide may be a fragment of 'gly-pro-arg' because a fragment thereof may be a single amino acid which is not a peptide? Please correct in order that one may readily ascertain what is being claimed. Likewise, claims 2-4 and 5-8 are ambiguous because they read on independent claim 1 wherein the peptide has not been clearly set forth.

Claim 5: The claim as written is ambiguous because it is difficult to read some of the bonds and atoms in the structure. In addition, it is unclear what "Aba*" stands for. Applicant is respectfully requested to submit a readable copy of the claim and define "Aba*" in order to clarify the record. Also, it is note that the claim does not contain a

period (.). Thus, it is unclear whether Applicant intended to add additional text to the sentence.

Claim 9: The claim as written is ambiguous because it is unclear whether Applicant intended the claim to depend upon claim 1 or not. Applicant is respectfully requested to clarify whether the claim is rightfully an independent claim or should depend upon another claim 1.

102 REJECTION

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Dean et al (US Patent No. 5,968,476).

Dean et al disclose technetium-99m labeled peptides useful for imaging thrombus sites in a mammalian body (see entire document, especially, abstract; column 10, lines 24-28). In addition, Dean et al disclose (1) the peptide reagents comprise a peptide having 4 – 100 amino acids and a technetium-99m binding moiety (column 4, line 34 – column 6, line 14). The peptides may be ligands for a polymerization site of fibrin. In a preferred embodiment, the peptides that are ligands for a polymerization site

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of fibrin comprise multiple copies of the sequence Gly-Pro-Arg-Pro (column 6, lines 17-31). Specifically, Dean et al disclose Sequence ID Nos. 30, 31, 32, and 33 along with the sequences [(GPRP)₂]K and [(GPRVVERHQSA)₂]K that contain the sequence Gly-Pro-Arg, represented as GPR (column 8, lines 54-62; columns 13-14, lines 1-18-22 and 55; claims 1, 7, and 8).

Thus, both Applicant and Dean et al disclose compositions comprising the peptide Gly-Pro-Arg having a radiolabel binding moiety and labeled with technetium-99m which is used to image thrombus.

103 REJECTION

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al (US Patent No. 5,968,476) in view of Kawasaki et al (Chem. Pharm. Bull., 41(5), 975-977 (1993)) and Laudano et al (Pro. Natl. Acad. Sci., USA, 75(7), 3085-3089 (1978)).

Dean et al (see discussion above) fail to disclose analogs and fragments of Gly-Pro-Arg which also bind fibrin and image thrombus.

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Kawasaki et al disclose terminal tripeptides of fibrin comprising Gly-Pro-Arg and their effect on fibrinogen/thrombin clotting (see entire document, especially, page 975, Table I; page 976, right column, second and third complete paragraphs; page 977, left and right columns).

Laudano et al disclose peptides that comprise Gly-Pro-Arg that bind fibrin (see entire document, especially, abstract; page 3085, right column, first and second paragraph). In addition, Laudano et al disclose analogs and fragments that bind fibrinogen (page 3086, Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Dean et al and generate various analogs (and fragments) of Gly-Pro-Arg which bind fibrin and image thrombus because all of the references disclose Gly Pro-Arg containing peptides that bind to fibrinogen. Furthermore, since Dean et al disclose the conjugating of a radiolabeling moiety and a radionuclide to Gly-Pro-Arg containing reagents, a skilled practitioner would be motivated to replace one peptide with another fibrin binding peptide to detect thrombus. Thus, since all the reference disclose peptides containing Gly-Pro-Arg, the references may be considered to be within the same field of endeavor; hence, the references are combinable.

SPECIFICATION

8. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This application is a 371 of

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PCT/US99/19011 filed 8/17/99 which claims benefit to provisional application number 60/096,803 filed 8/17/98." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

COMMENTS/NOTES

9. It should be noted that no prior art has been cited against claims 5 and 6. However, Applicant MUST address and overcome the 112 rejections above.

Note: Claim 5 is allowable over the prior art of record because the prior art neither anticipates nor renders obvious a composition of claim 5 having the additional limitations of claims 1 and 3. In regards to claim 6, the claim is distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a composition of formula I or II wherein the peptide comprise Gly-Pro-Arg in combination with a radiolabeling moiety, Gly-Ala-Gly-Gly, and a radionuclide.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "D. L. Jones", is positioned above the printed name.

D. L. Jones
Primary Examiner
Art Unit 1616

July 7, 2003